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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,006	08/24/2000	Patrick Tso	10738-17	5310

7590 06/30/2004
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Cincinnati, OH 45202

EXAMINER

MITRA, RITA

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,006

Applicant(s)

TSO ET AL.

Examiner

Rita Mitra

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-14,19 and 63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-14,19 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The request filed on March 23, 2004 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/623006 is acceptable and an RCE has been established. An action on the RCE follows.

Status of the Claims

Applicants' amendment and response to office action dated December 3, 2003, filed on March 23, 2004, is acknowledged. Claims 1, 4-14 and 19 have been amended. Claims 2, 3, 15-18 and 20-62 have been canceled. New claim 63 has been added. Therefore, claims 1, 4-14, 19 and 63 are currently pending and are under examination.

Response to Remarks and Arguments

Rejection of claims 1, 4-14, 19 and 63 under **35 U.S.C. § 112, First Paragraph** is withdrawn in view of Applicants' amendments to claims and remarks at pages 5-7.

New grounds of rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-14, 19 and 63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 4, 13, 14 and 63 encompass the subject matter that is not defined in the specification. The claims are directed to a method for inhibiting lipid oxidation associated with a condition in a patient, comprising administering to a patient a composition comprising a pharmacologically effective amount of an apolipoprotein (apo) A-IV peptide or derivative, analog, homolog, or fragment thereof, to inhibit lipid oxidation. Additionally the claimed invention asserts that the apolipoprotein A-IV is a peptide sequence of from 6-71 amino acids in length and wherein the peptide or derivative, analog, homolog, or fragment thereof has substantially the same lipid oxidation properties as the apolipoprotein A-IV molecule, however, the specification, only discloses cursory conclusions (see page 6, lines 3-6), without data to support the findings, which state that a number of novel lipid oxidation suppressant peptides, derived from apolipoprotein A-IV, have been made, these peptides possess lipid oxidation inhibiting properties which when administered orally or intravenously, can be used to decrease atherosclerosis. The specification at pages 6-9 and 12-15 provide a limited discussion of the derivative, analog, homolog or fragment. As it is stated at page 12 that the invention provides for a number of lipid oxidation inhibiting peptides of approximately 5-90 amino acids in length, which substantially correspond in sequence to amino acid sequence found in specific portions of apo AIV, which is insufficient description as no characteristics are provided nor any evidence to demonstrate retention of function with regard to inhibitory activity in lipid oxidation.

Claim 4 is directed to the method of claim 1, wherein the peptide has an amino acid sequence comprising amino acid sequence set forth in SEQ ID NO: 5 or a derivative, analog, homolog or fragment of the said sequence. However, the specification provides only a generic description of how a variety of derivative, analog, homolog or fragment can be generated (page 22-26), no specific guidance is provided on the generation of the derivative, analog, homolog or fragment that demonstrate the biological activity of the peptide sequence of SEQ ID NO: 5

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the apolipoprotein AIV, which comprises derivative, analog, homolog or fragment,

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which have substantially the same lipid oxidation properties as the apolipoprotein AIV wild-type molecule. Furthermore, there is no written description of either a representative number of the variants or of a common structural feature of the apo AIV wild-type which encompasses all the variants.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-14 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Qin et al. ("Apolipoprotein A-IV: A potent endogenous inhibitor of lipid oxidation," FASEB Journal, vol 12, N4, 1, S, page A341, Presentation NO: 1980, March 17, 1998). Qin et al. teach the role of ApoA-IV as an endogenous inhibitor in protection against lipid oxidation. Qin et al. demonstrated anti-oxidative activity of apo A-IV by using fasting intestinal lymph to mimic conditions in the interstitial fluid, the potential site for lipoprotein oxidation in vivo. Qin et al. further teach 10 µg/ml of apo A-IV significantly inhibited Copper-mediated oxidation of lymph lipoproteins. This inhibitory effect was further evaluated using purified LDL. Qin et al also teach an addition of apo A-IV (2.5 µg/ml) that increased the time of 50% conjugated diene formation by 2.4 fold. Apo A-IV also protected Macrophage-induced oxidation of fasting lymph, and also protected against atherosclerosis (see entire abstract), thus anticipating claims 1, 4-14 and 19 of instant application. Qin et al.'s ApoA-IV is considered for the apolipoprotein A-IV compound of claim 1 and dependent claims 4-14 and 19 of instant application.

Conclusion

No claim is allowed.

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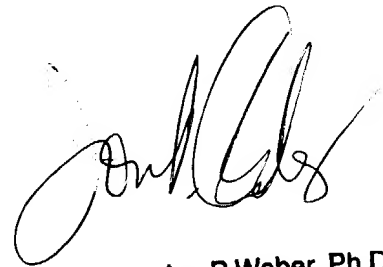
Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (571) 272-0951. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.



Rita Mitra, Ph.D.

June 22, 2004



Jon P. Weber, Ph.D.
Primary Examiner